Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of consultation based on PLISSIT model on Family Function and Sexual Quality of Life in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of counseling based on PLISSIT model on family performance and sexual quality of life in patients with multiple sclerosis

Design

This study is a clinical trial with two groups (intervention and control), double blinded (the data analyst and participants) and randomized, with 30 patients in each group. In the intervention group, 4 counseling sessions Based on the PLISSIT model over 4 weeks And a 90-minute session per week is done individually; While control group patients will receive routine procedures. Family performance score and The Sexual Quality of Life score will be measured before and after the intervention.

Settings and conduct

This double blinded study (the data analyst and participants), will be done in the Kerman Medical Center of the Special Diseases.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women who complain of sexual dysfunction Ability to communicate in Persian language Diagnosis of Multiple Sclerosis according to neurologist confirmation Continuous attendance at counseling sessions Exit criteria: Failure to attend one of the meetings and the occurrence of a stressful incident Cases of recurrence of symptoms during the intervention so that it can be effective in our intervention Pregnancy, lactation or Pregnancy desire Suffering from other mental and physical illnesses Addiction to alcohol and drugs, according to the patient History of genital and breast surgery

Intervention groups

In the intervention group, 4 counseling sessions Based on the PLISSIT model over 4 weeks And a 90-minute session per week is done individually; While control group patients will receive routine procedures. Family performance score and The Sexual Quality of Life score will be measured before and after the intervention.

Main outcome variables

family performance and sexual quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N9**
Registration date: **2020-04-28, 1399/02/09**
Registration timing: **retrospective**

Last update: **2020-04-28, 1399/02/09**
Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-12-31, 1398/10/10

Actual recruitment end date

2020-03-08, 1398/12/18

Trial completion date
2020-04-08, 1399/01/20

Scientific title
The effectiveness of consultation based on PLISSIT model on Family Function and Sexual Quality of Life in patients with multiple sclerosis

Public title
The effectiveness of Sexual counseling on Family Function and Sexual Quality of Life in patients with MS

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Married women who complain of sexual dysfunction Ability to communicate in Persian language Diagnosis of Multiple Sclerosis according to neurologist confirmation Continuous attendance at counseling sessions

Exclusion criteria:
Failure to attend one of the meetings and the occurrence of a stressful incident Cases of recurrence of symptoms during the intervention so that it can be effective in our intervention Pregnancy, lactation or Pregnancy desire Suffering from other mental and physical illnesses Addiction to alcohol and drugs, according to the patient History of genital and breast surgery

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate the subjects to the intervention and control groups, a randomized classification method is used, so that people in terms of Family performance score, Quality of sex life score, drug use by patients, type of disease, duration of illness, etc. are divided into groups. Subsequently, through the use of a simple method and using Excel software from each group, half of the subjects are placed in the intervention group and the other half are in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants and data analyst do not know which data is related to the intervention group and which data is related to the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Medical Center of the Special Diseases, No. 78 Alley, Shahid Rajaee Street,

City
kerman

Province
Kerman

Postal code
7619875994

Approval date
2019-10-21, 1398/07/29

Ethics committee reference number
IR.KMU.REC.1398.303

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Family Function score

Timepoint
The Family Function score will be measured before and after the intervention at the end of the fourth week.

Method of measurement
Family functioning scale

2

Description
Sexual Quality of Life score

Timepoint
Sexual Quality of Life score will be measured before and after the intervention at the end of the fourth week.

Method of measurement
Sexual Quality of Life–Female Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:They receive 4 counseling sessions over 4 weeks, one 90-minute session per week, individually and face-to-face.The PLISSIT model will be used for consultation.The content of the counseling sessions includes the following:Session 1: Opportunity to Patient (P): At this stage, the therapist allows the patient to maintain the correct sexual traditions in order to remain sexually active, and at the same time encourages the patient to discuss the problems that It damages her sexual function. Session 2: Limited Information (LI): The patient is given information about the anatomical and physiological aspects of sexual function and information about MS and its side effects on sexual function.Session 3: Specific Suggestions (SS): At this stage, specific suggestions for the patient's specific concerns, counseling on the choice of alternative sex positions, and strategies to improve sexual satisfaction are provided.Session 4: Intensive Care (IT): In a few cases where people have underlying causes in their sexual problems that cannot be resolved in the first 3 steps, intensive treatment will be needed. By identifying these situations, the researcher will refer the patient to a specialist.

Category
Other

2

Description
Control group: Patients in the control group received routine methods such as exercise, relaxation techniques, etc.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical Center of the Special Diseases

Full name of responsible person
Batool Tirgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Batool Tirgari

Position
Associate professor

Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable